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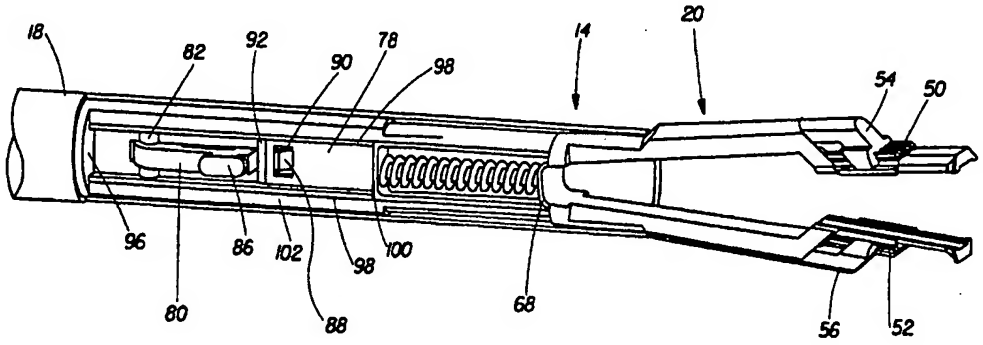

(57) Abstract

An anastomotic coupler (10) includes an elongated body (12) having a head end (14) and a control end (16). At least two jaws (38, 40) for engaging the tubular tissue vessels to be connected are located at the head end (14). Control of the jaws (38, 40) and advancement of a staple cartridge (46, 48) and driver (54, 56) are achieved remotely from the control end (16) of the elongated body (12).

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ANASTOMOTIC COUPLER

Related Applications

This application claims priority to U.S. Provisional Application Serial Numbers 60/057,912 filed September 4, 1997, and 60/074,381 filed February 11, 1998.

Technical Field

This invention relates to a device for inserting surgical staples in an anastomotic coupling. Specifically, it provides a single-use staple cartridge which can be replaced on a multiple- use, single-procedure instrument.

Background of the Invention

Anastomosing (i.e., joining or connecting) tubular structures is an essential part of many surgical procedures. Currently, surgical devices are available which connect larger lumen (i.e., diameter) tubular structures together, generally in the esophageal, gastric and intestinal tracts. The use of these devices has been limited, however, to traditional open surgical procedures. With the trend towards less-invasive, lower trauma procedures, the need has increased for an analogous device that can join together smaller lumen structures such as veins and arteries. Despite the efforts of many developers, and the presence of other patents, such as U.S. Patent No. 4,930,674, directed toward solving this problem, no such small lumen anastomotic device has gained clinical acceptance. None of the current devices satisfy the following five criteria.

The first is reduced technique sensitivity. Manual suturing of vessels requires a great deal of manual dexterity and acquired skill. The ideal device can be used by a high percentage of surgeons without an inordinate amount of training and practice.

The second is reduced time. Connecting a number of vessels in a single surgical procedure can be time-consuming and laborious. This can lead to surgeon fatigue and increased patient risk. The ideal device should reduce the time to complete an anastomosis.

Third, it provides intima-to-intima closure. While it is much easier to join the external surfaces of vessels to one another, long-term patency and tissue viability are compromised. The ideal device would uniformly connect the internal surfaces (intima) of vessels via an everted anastomosis.

Fourth, it provides secure, patent closure. The ideal anastomotic device must join the vessels securely enough to prevent leaking without overly traumatizing the tissue and with a high level of reliability. This includes achieving consistantly accurate alignment of the surgical staples and the staple-forming surfaces of the anvil.

Fifth, it must be economic to use. Cost containment pressures make it important that the ideal device be designed in a manner that minimizes its cost on a per-procedure basis.

Summary of the Invention

The present invention is a reusable or disposable anastomotic coupler surgical device that satisfies the above five criteria and may be used on either small or large lumen vessels. The present invention may be constructed for either single-procedure or multi-procedure use. The single-procedure version is disposable (i.e., thrown away after one procedure) and can be configured to be used either once or multiple times within the one procedure. The multi-procedure version is reusable (i.e., capable of being processed to permit its use in multiple procedures) and can be used multiple times within a single procedure. To permit multiple applications, individual components may be disposable or reusable.

Brief Description of the Drawing

Like reference numerals are used to indicate like parts throughout the various figures of the drawing, wherein:

Fig. 1 shows a pictorial view of a preferred embodiment of the present invention;

Fig. 2 shows a pictorial close-up of the head and an preferred embodiment;

Fig. 3 shows a longitudinal sectional view of a replaceable staple cartridge according to a preferred embodiment of the present invention in an open position;

Fig. 4 shows a view similar to Fig. 3 wherein jaws of the replaceable staple cartridge are in a closed position;

Fig. 5 shows a view similar to Fig.3 & 4 in which the staple housing is advanced forward toward the anvil;

Fig. 6 shows a view similar to Figs. 3-5 wherein the staple pusher is advanced forward to drive legs of the staples into the forming surface of the anvil;

Figs. 7-9 shows a preferred mechanism for inserting and engaging a disposable staple cartridge according to a preferred embodiment of the present invention;

Fig. 10 is an exploded view showing the internal parts of the elongated body;

Fig. 11 is a longitudinal sectional view of the control end of the present invention;

Figs. 12-14 are enlarged views of the head portion an alternate embodiment according to the present invention;

Fig. 15 shows a manner in which a mobilized vessel is placed within the jaws;

Figs. 16 & 17 show the manner in which the open end of vessel is everted over the anvil flanges for anastomosis with the end or side of another vessel; and

Figs. 18-20 show sequential sectional views of an end-to-side anastomosis.

Detailed Description of the Preferred Embodiment

In a preferred embodiment of the invention, the disclosed surgical instrument can connect large or small lumen vessels in either an end-to-end or an end-to-side manner by:

1. Grasping the first vessel near its ligated end with a rotatable pair of jaws that are flanged at their ends.

2. Closing the jaws and everting the end of the first vessel back and over the flanged end of the closed jaws, using a purse string suture when necessary to facilitate the eversion and to secure the end of the vessel around the flanged end.

3. a. End-to-Side Anastomosis — Inserting the flanged end of the first vessel into an incision along the longitudinal axis of the second vessel.

   b. End-to-End Anastomosis — Inserting the ligated end of the second vessel over the flanged end of the jaws containing the everted end of the first vessel.

4. Advancing the staple cartridges and staple drivers aligned on both jaws until the vessels are trapped between the inner surface of flanged head of the jaws and the staple cartridges.

5. Advancing the staples in the staple cartridge until the staple legs pass through the trapped tissue and are bent inward by the forming surfaces located on the inner surface of the flanged end of the closed jaws.

6. Retracting the staple cartridges and staple drivers, and opening the jaws, releasing the joined (i.e., anastomosed) vessels.

7. If the device is either a single-procedure, disposable multi-use device or a multi-procedure, reusable device, replacing the spent empty staple cartridges with cartridges containing staples.

8. If the device is a reusable device, processing the instrument in order to permit its use in multiple procedures

In a preferred embodiment of the present invention, the instrument may be disposable (single procedure use) or reusable (multiple procedure use). Both versions function in the same manner by connecting vessels with the interaction of six structural elements:

1. A pair of jaws containing integral flanges at their ends.

2. A staple cartridge and driver on each jaw which are connected to each other as well as to their respective jaws.

3. A means for controllably advancing the cartridge/driver assemblies on the closed jaws.

4. A means for advancing the staple drivers in order to drive the legs of the staples through the vessels at the point where they are to be anastomosed.

5. (optional) A means for rotating the shaft of the instrument.

6. A means for replacing the spent (i.e., fired) staple cartridges with new cartridges containing staples.

Referring to the various figures of the drawing, and first to Fig. 1, therein is shown at 10 a device according to the preferred embodiment of the invention. The device 10 includes an elongated body 12 having a head end 14 and a control end 16. The elongated body 12 includes a hollow barrel 18 through which control actuation members pass to connect control triggers to various components of the staple cartridge 20 at the head end 14.

Generally, the control end 16 includes a jaw-closing trigger 22 which is movable toward the main instrument body 24 as shown by arrow 25. The movement advances member 26 to remotely operate jaws of the head portion 14 into a closed position. In the closed position, a handle latch 28 will releasably engage with a main body latch component 30 such that closure of the jaws is firmly, but releasably, achieved.

A second component of the control end 16 is the cartridge/driver advancement knob 32. Rotation of this knob 32 causes the staple cartridge and driver to advance against tissue, clamping it against an anvil portion of the jaws (described below).

The final component of the control end 16 is the firing trigger 34. Movement of the trigger 34 toward a transverse handle 36 will result in firing of the disposable staple cartridge.

Referring now to Fig. 2, therein is shown a pictorial view of the head end 14 of a preferred embodiment of the invention. The head end includes a pair of jaws 38, 40 each having an axially-directed, aligned groove 42, 44 which, when the jaws 38,40 are closed, creates an axially-oriented passageway 45. On each jaw 38, 40 is mounted a staple cartridge 46, 48 which includes a staple-carrying housing 50, 52 and a driver member 54, 56.

Referring now also to Figs. 3-6, therein is shown a longitudinal sectional view of the entire disposable staple cartridge/jaw unit 58 in sequential stages of operation.

Fig. 3 shows the jaws 38, 40 in an open position. As the tubular barrel 18 of the elongated body is advanced relative to the staple cartridge 58 (or staple cartridge 58 is retracted relative to the barrel 18), the jaws are moved together into a closed position as shown in Fig. 4. Referring to Fig. 5, the cartridge unit 46, 48 is advanced forward so as to clamp layers of tissue to be coupled against the outwardly-extending flange or anvil 60 of the jaws 38, 40. Advancement of this cartridge unit 46 causes spring 62 to be compressed. The purpose of this spring 62 is to retract the staple cartridge unit 46 after firing.

Fig. 6 shows the unit 58 in the fired position. In this position, the staple drivers 54, 56 have been axially advanced relative to the staple housing 50,52 so as to drive legs of the staples against a forming surface on the anvil flange 60.

In preferred form, the entire staple cartridge unit 58, with the exception of the staples themselves and possibly the spring 62, is made of surgical or spring steel or may be made of a thermoplastic or polymeric material. The two halves of the jaws 38, 40 are hinged together at a bight portion 68 which includes "living" hinges. A "living" hinge indicates a portion which is constructed of like material but which is shaped and sized to be particularly flexible relative to the rest of the member. A medial portion 70 of the staple housing unit also includes "living hinges" which allows it to flex with the jaws 38, 40 during opening and closing.

As shown in Fig. 5, the driver members 54, 56 are advanced with the staple housing portions 50, 52 by engagement of notches 72, 74 against proximal ends of the driver members 54, 56. As shown in Fig. 6, the driver members 54, 56 are independently axially advancable relative to the staple housing 50, 52 so as to advance the surgical staples out of channels 53 in the staple housing 50, 52, through the tissue to be connected and against the anvil 60. As can be appreciated by a comparison of Fig. 2 to Figs. 3-6, an axially-oriented passageway 76 is provided to guide the longitudinal advancement of the respective members of the staple cartridge unit 58. This novel structure assures that the staple housing 50, 52 and each individual staple is correctly aligned

against the anvil 60 and each staple-forming surface when advanced against tissue to be joined. This is important because current devices are subject to rotational misalignment.

One feature provided by a preferred embodiment of the present invention is that the staple cartridge/jaw unit 58 is easily and quickly replaceable. A preferred mechanism for achieving this feature is illustrated in Figs. 7-9. A tang portion 78 of the unit 58 is inserted into the open end of the barrel 18. The tang includes a opening or notch which engages a hook or pawl of a hinged engagement member 80. Engagement member 80 pivots on an internal pivot pin 82 and is spring biased into engaging position by a resilient spring member 84. A button portion 86 projects outwardly through an opening 88 in the barrel 18 such that it can be manipulated by the user to release engagement between the pawl member 88 and the opening or notch 90 in the tang 78.

Also in preferred form, the tang portion 78 is relatively flat or includes flat portions such that the rotational orientation of the cartridge unit 58 may be controlled relative to the barrel 18. The extreme end 92 of the tang 78 may be beveled on one or both sides so as to ease engagement with the pawl member 88. If desired, this bevel can be designed to restrict the orientation of the replaceable unit 58 to designate a particular "up" side or may be designed such that no particular orientation is required. The entire jaw assembly can be rotated by turning a jaw assembly rotating knob 94.

Referring to Fig. 10, therein is shown an exploded view of the elongated body 18, disposable staple cartridge unit 20 and internal control members. These members include a staple cartridge assembly puller shaft 96 which grips the replaceable staple cartridge unit 20 and advances or retracts it relative to the barrel 18 in response to rotation of the control knob 32. A pair of cartridge-positioning bars 98 bear against a proximal end 100 of staple cartridge housing 50 for advancement of the staple cartridge housing 50 52, and pusher members 54, 56 relative to the jaws 38, 40. This can be seen clearly in Figs. 6 & 8. Advancement of these members 98 causes compression of the spring 62. The spring biases the end 100 back when the control bars 98 are retracted. A pair of pusher control bars 102 are used to advance the pushers 54, 56 independently of the staple cartridge housing 50, 52 for firing.

Referring now to Figs. 12-14, therein is shown an alternate design of the preferred embodiment of the present invention. In this alternate design, the central axial passageway 45 is shaped to be greater in depth than its width relative to the jaws 38, 40 additionally, an annular groove 104 is formed at the base of the anvil flange 60. This groove 104 provides space for edges of the tissue being anastomomically joined to prevent damage thereto and helps to maintain alignment of the staple cartridge housing 50, 52 relative to staple forming surfaces 106 of the anvil face. In all respects, the version of Figs. 12-14 is the same and, therefore, will be used to explain detail of the staple cartridge unit.

Each cartridge is preloaded with a series of surgical staples 108 which are symmetrically aligned around the jaws when closed. Each staple 108 will typically include a pair of legs and a connector portion there between. The staples 108 are held in grooves 53 which axially-align the staple legs in orientation toward the anvil surface 60. The staple pushers 54, 56 include projections into the grooves 53 in order to symmetrically and evenly drive or push the staples 108 forwardly out of the groove, through the tissue being connected, and into the staple-forming surface 106 of the anvil 60.

Referring now to Figs. 15-20, the first step in the operation of the instrument 10 is to grasp the first vessel 110 with the instrument jaws 38, 40. This may be done externally to the body (*ex vivo*) if the vessel 110 is sufficiently mobilized. The jaws 38, 40 are closed around the first vessel 110, trapping it in the passageway 45, and causing the flanges 60 at the jaw ends to come together. The captured vessel 110 is ligated at an angle a short distance beyond the flanged end of the jaws 38, 40. Using a purse string suture, if necessary, the end of the vessel is pulled back over the flanged end 60 of the jaws 38, 40, everting and securing the vessel 110. The rotatable shaft is used to facilitate positioning the jaws and to improve visibility.

For an end-to-side anastomosis (Figs. 18-20), a longitudinal slit is placed in the second vessel at the point where the anastomosis is to occur. The slit should be kept as small as possible. The flanged head 60 of the jaws 38, 40 upon

which the everted end of the first vessel 110 is located is inserted into the slit in a manner similar to inserting a button into a buttonhole. For an end-to-end anastomosis, the prepared end of the second vessel is positioned over the everted end of the first vessel.

Once the vessels have been properly positioned, the staple cartridge 50, 52 and driver assemblies 54, 56 on both jaws 38, 40 are advanced until the two vessels are trapped between the staple cartridge 50, 52 and the flanged end 60 of the closed jaws 38, 40 at the point where the anastomosis is to occur. The staple drivers 54, 56 move forward, advancing the staple legs through the vessels 110, 112 until they bend against the staple forming surface 106 on the flanged end 60 of the jaws 38,40.

Once the staples have formed, the staple firing trigger is released, the staple firing return spring 62 expands, the staple cartridges 50, 52 and drivers 54, 56 are retracted and the jaws 38, 40 are opened, releasing the joined vessels 110, 112. The surgeon can then remove the instrument 10 from the anastomotic site. The empty staple cartridge 58 can then be replaced when necessary to permit multiple actuations.

It is to be understood that many variations and modifications of the disclosed preferred embodiment may be made without departing from the spirit and scope of the inventions. It is to be understood that the invention concept is greater in scope than the embodiments described above and that patent rights are to be defined by the following claim or claims interpreted according to accepted

doctrines of claims interpretation, including the doctrine of equivalents and reversal of parts.

What is claimed is:

1. An anastomotic staple coupler, comprising:

an elongated body having a head end and a control end;

at least two jaws at the head end which when open allow lateral access between the jaws and when closed form a axial passageway for receiving a first tubular tissue vessel;

an anvil on each jaw in the form of an outwardly-directed flange having a staple-forming surface; and

an axially-advancable staple cartridge associated with each jaw including a plurality of surgical staples aligned in a staple housing and a driver, axially-advanceable independent of the staple cartridge as a whole, positioned to drive legs of the staples through the tissue and against the anvil for coupling of first and second tubular tissue vessels;

wherein opening and closing of the jaws, advancement of the staple cartridge and advancement of the driver being actuated remotely from the control end of the elongated body.

2. The device of claim 1, wherein the jaws and staple cartridge releasably engaged to the body such that they can be removed and replaced as a pre-loaded single-use disposable unit.

3. The device of claim 2, wherein the pre-loaded single-use disposable unit includes an elongated tang which is engaged by a holding means at the head end of the body.

4. The device of claim 3, wherein an actuator for releasing engagement of the holding means extends outwardly of the body.

5. The device of claim 2, wherein the jaws are hinged relative to one another at a proximal end.

6. The device of claim 1, wherein the jaws are hinged relative to one another at a proximal end.

7. The device of claim 1, wherein the staple-forming surface is directed axially toward the control end of the body.

8. The device of claim 7, wherein the anvil includes an annular groove radially inwardly of the staple-forming surface.

9. The device of claim 1, wherein the axial advancement of the staple cartridge is selectively controlled from the control end of the body.

10. The device of claim 1, wherein the body includes an axial passageway through which control actuators extend from the control end to the head end for remotely controlling closure of the jaws.

11. The device of claim 10, further comprising control actuators extending through the passageway to remotely and independently control advancement of the staple cartridge and driver.

12. The device of claim 1, wherein rotational orientation of the jaws is controlled from the control end of the body.

13. The device of claim 1, wherein the staple cartridge includes axially-oriented grooves for guiding the staples.

14. The device of claim 1, wherein the staples are evenly spaced circumferentially around the jaws when closed.

15. The device of claim 1, wherein each jaw includes an axially-oriented guide for mating each staple to a correponding staple-forming surface.

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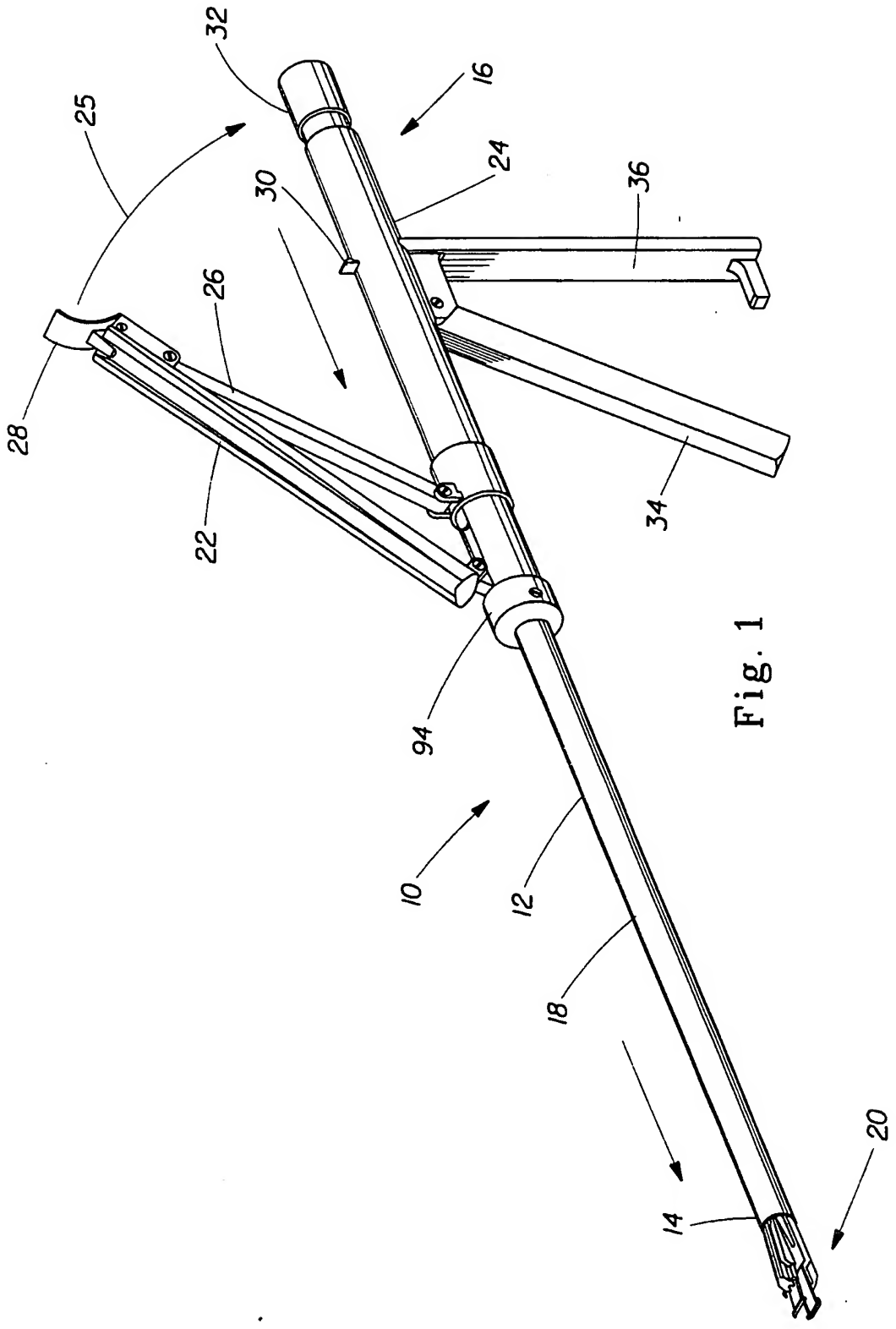

Fig. 1

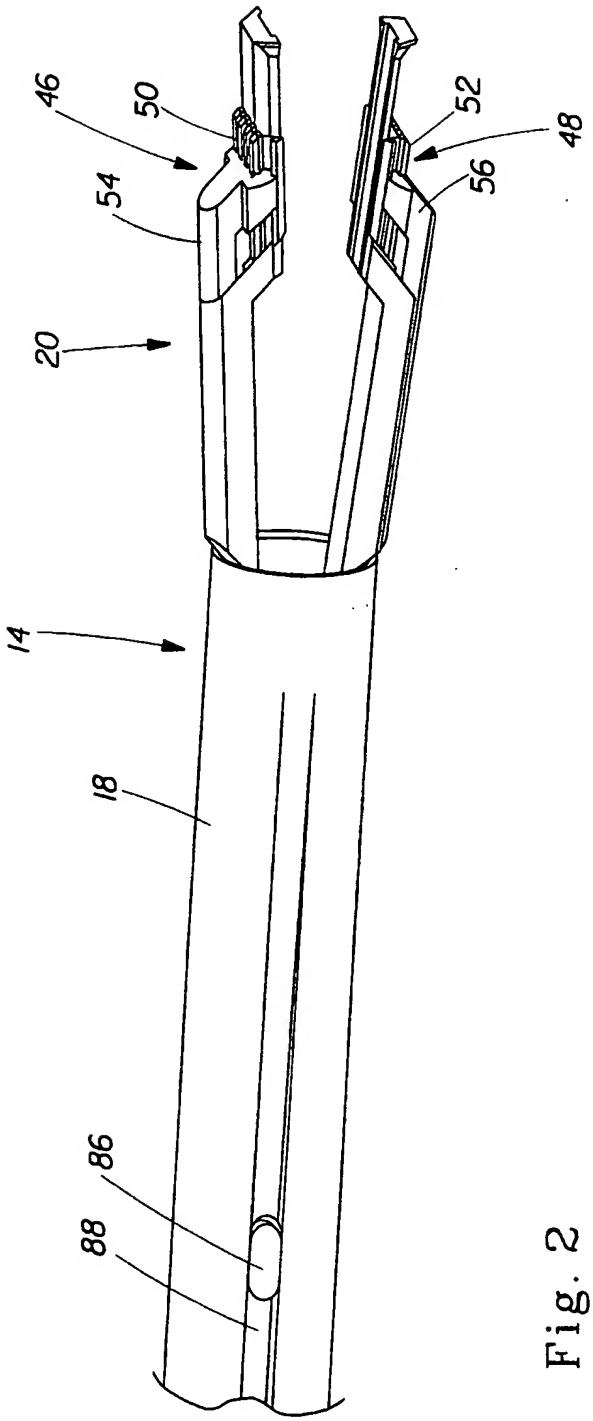

Fig. 2

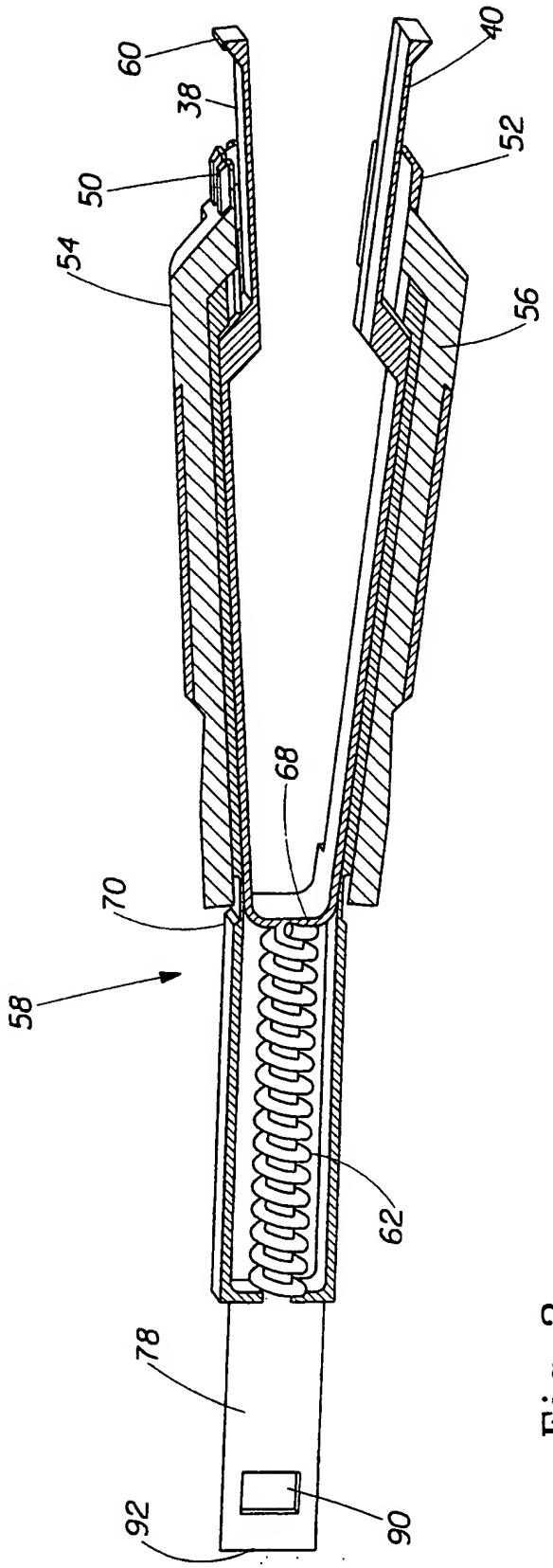

Fig. 3

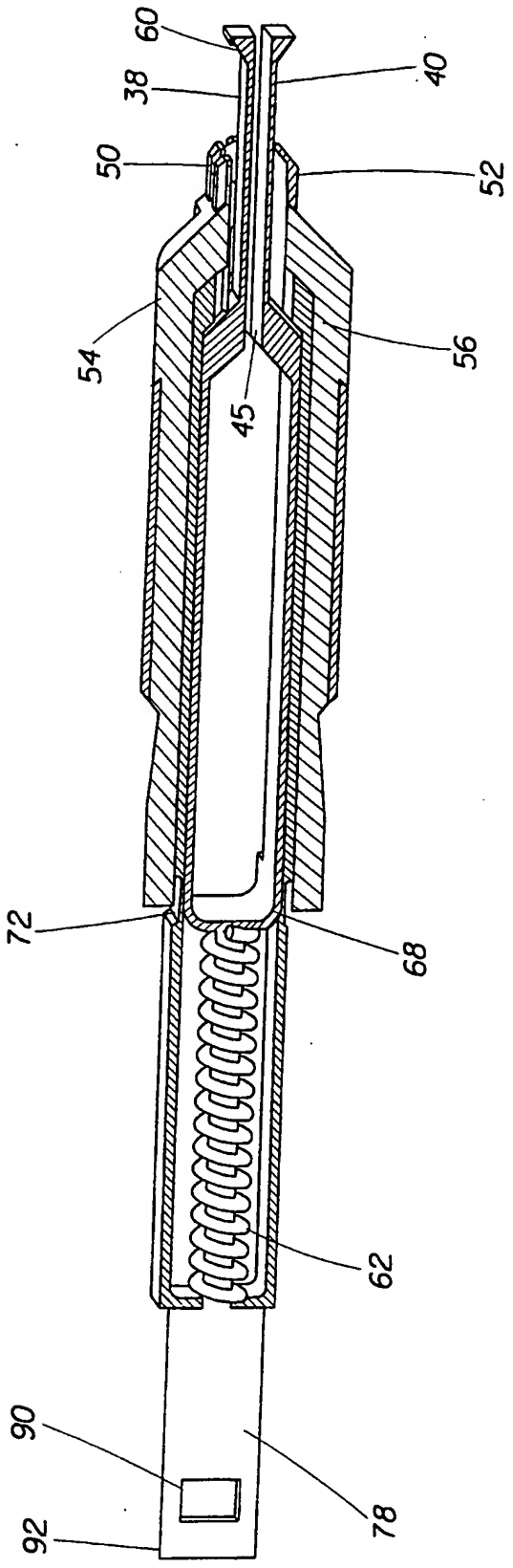

Fig. 4

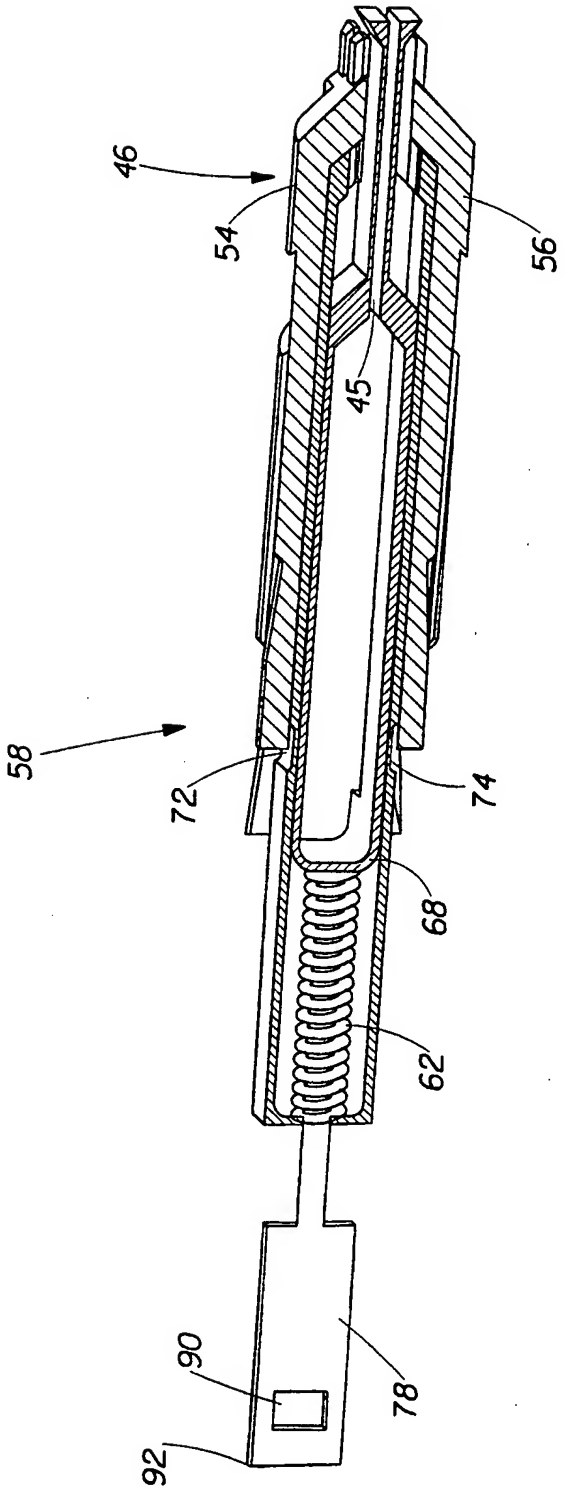

Fig. 5

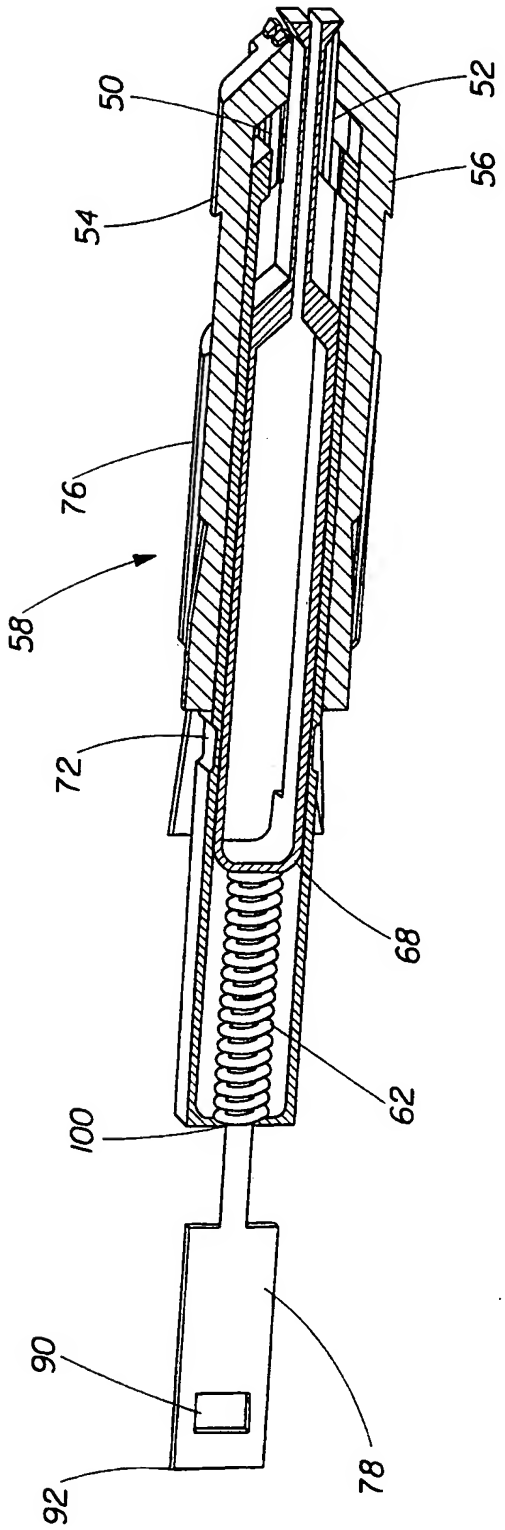

Fig. 6

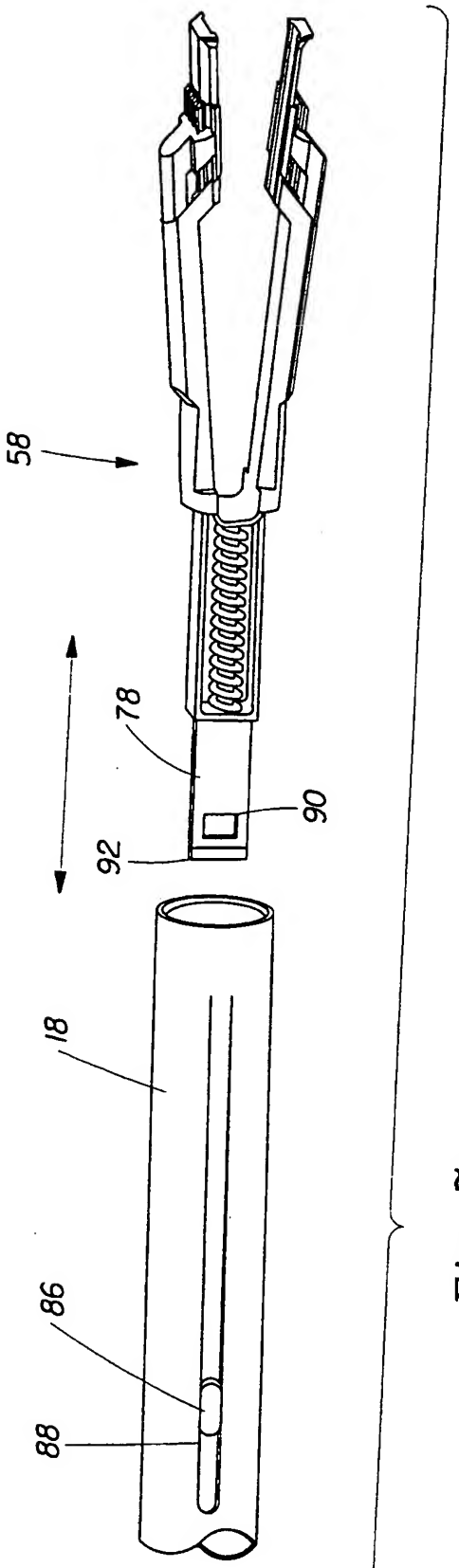

Fig. 7

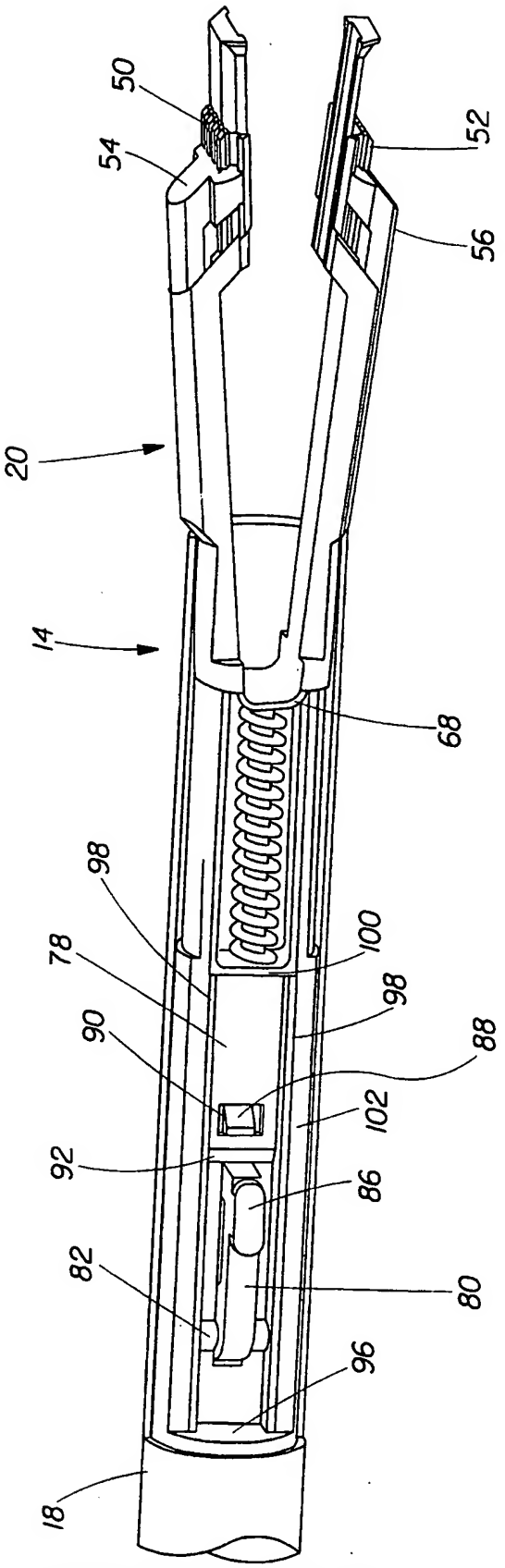

FIG. 8

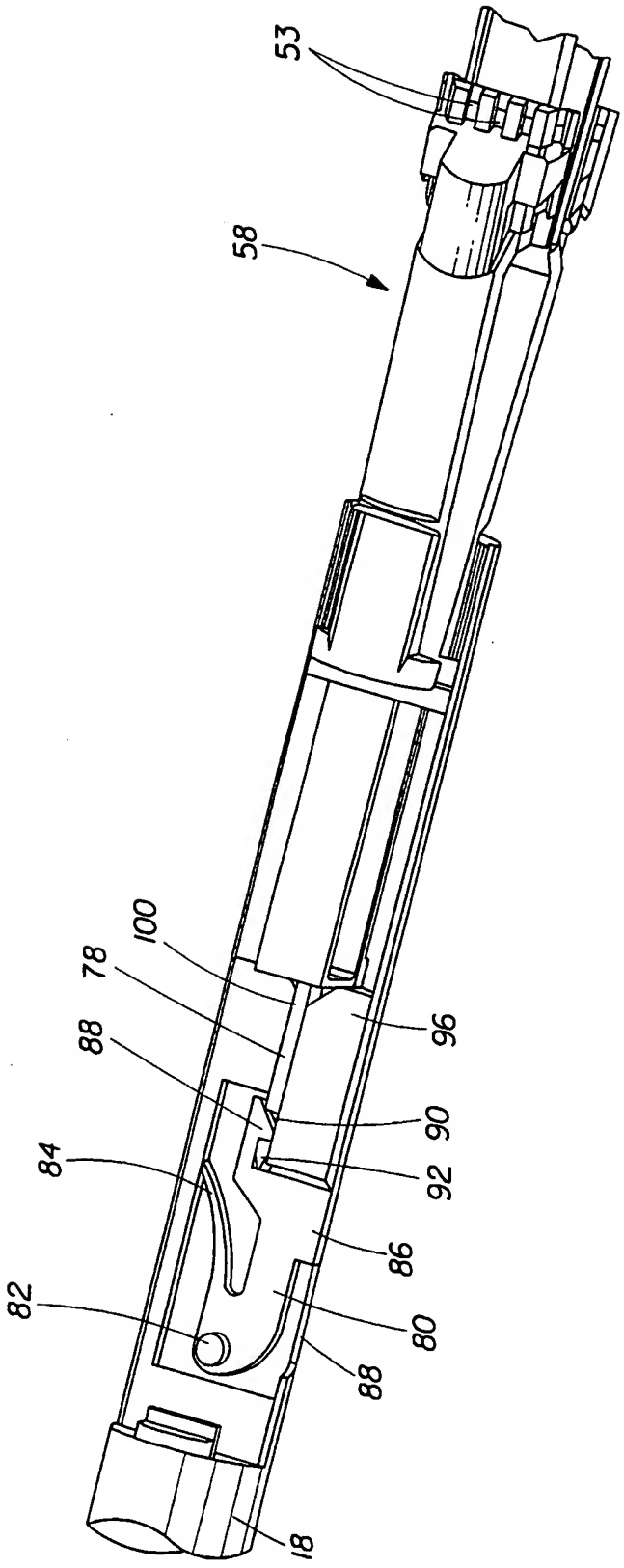

Fig. 9

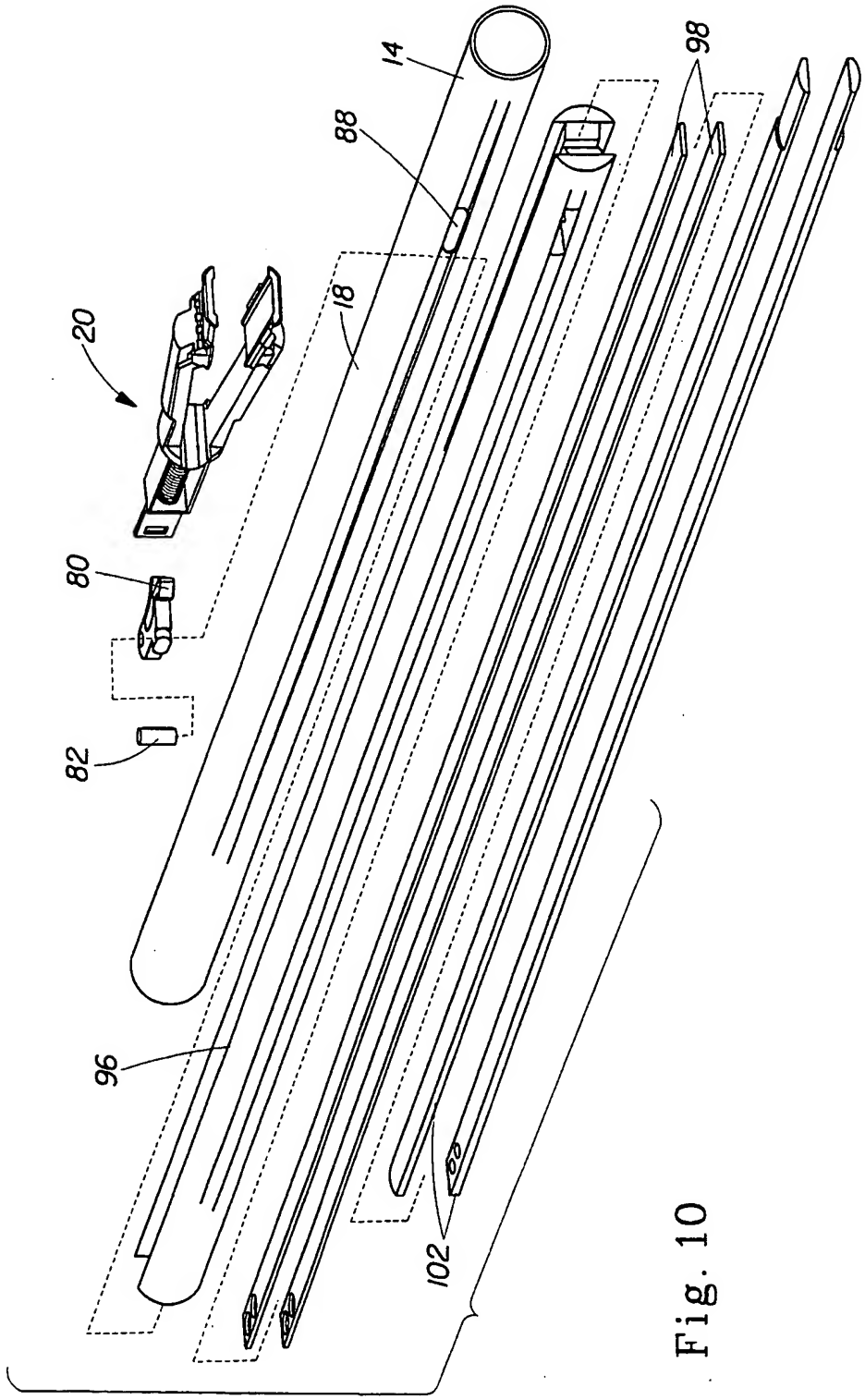

Fig. 10

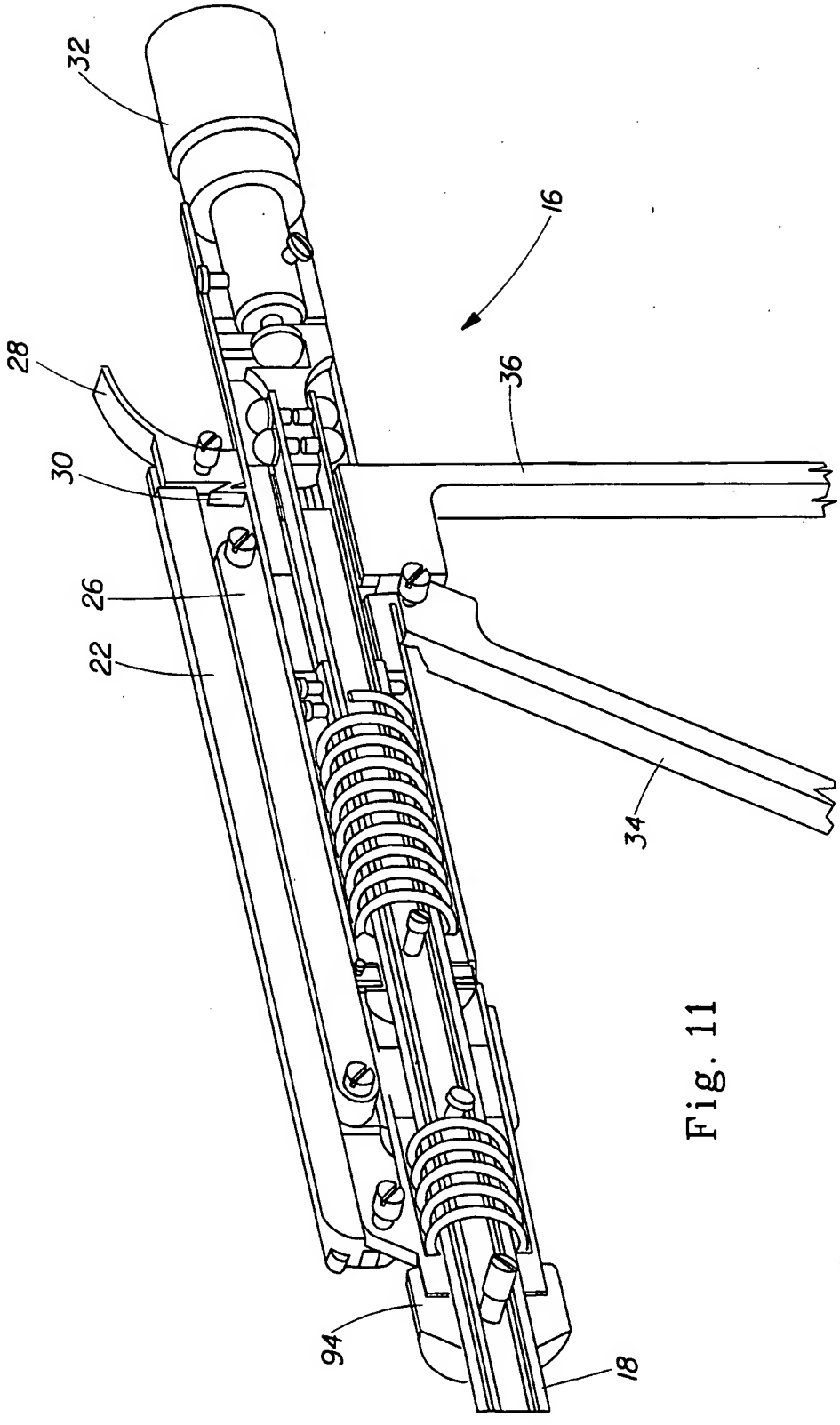

Fig. 11

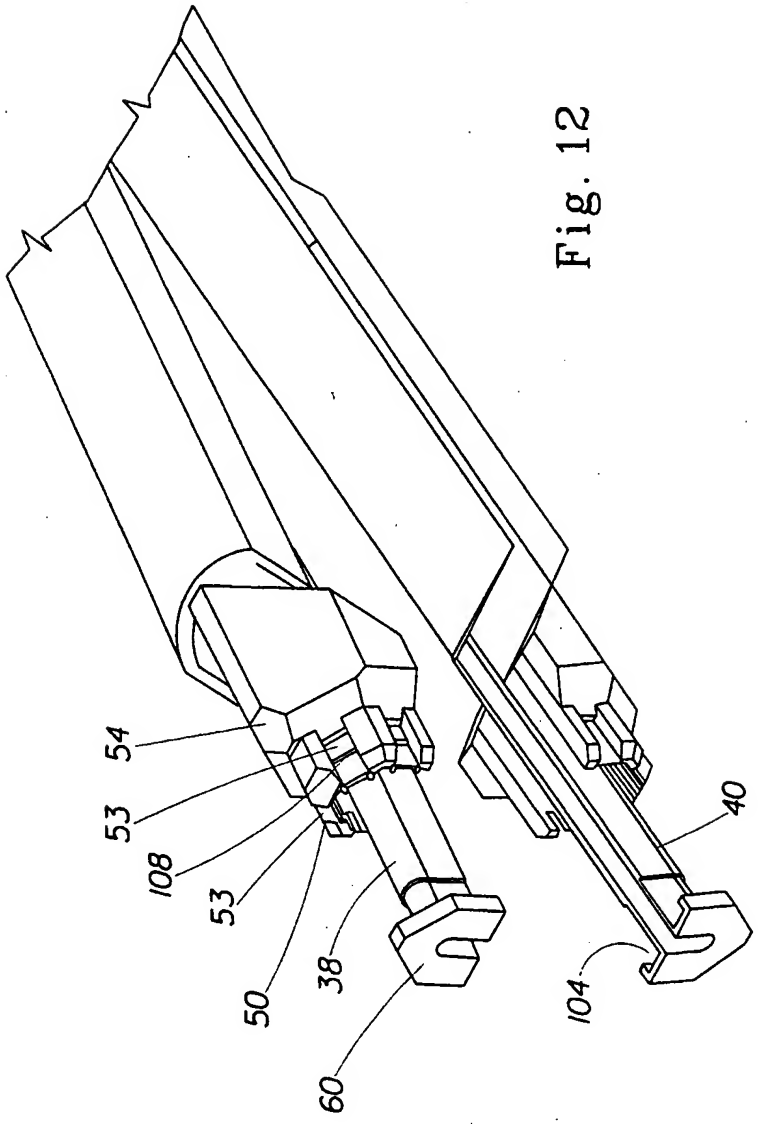

Fig. 12

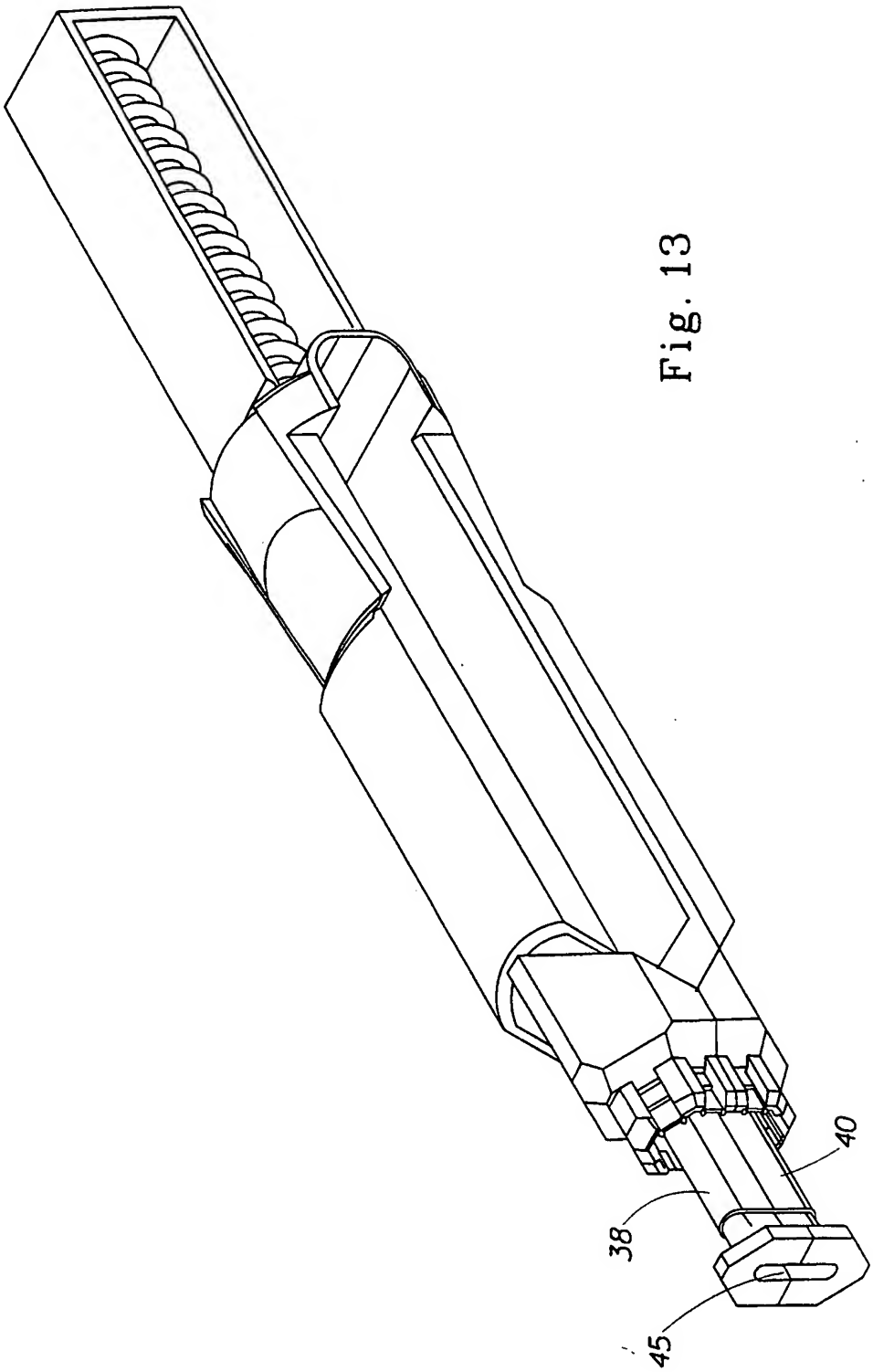

Fig. 13

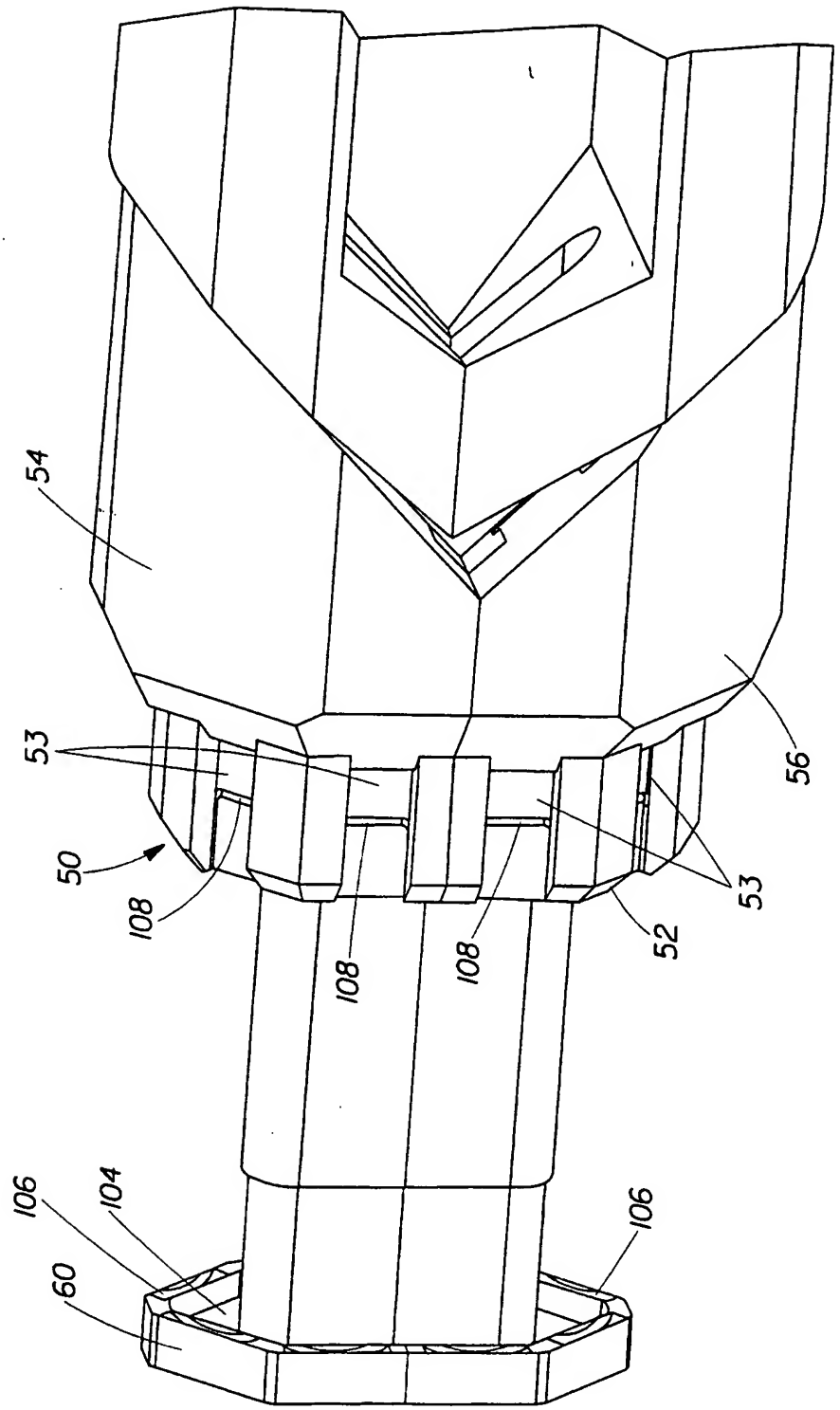

Fig. 14

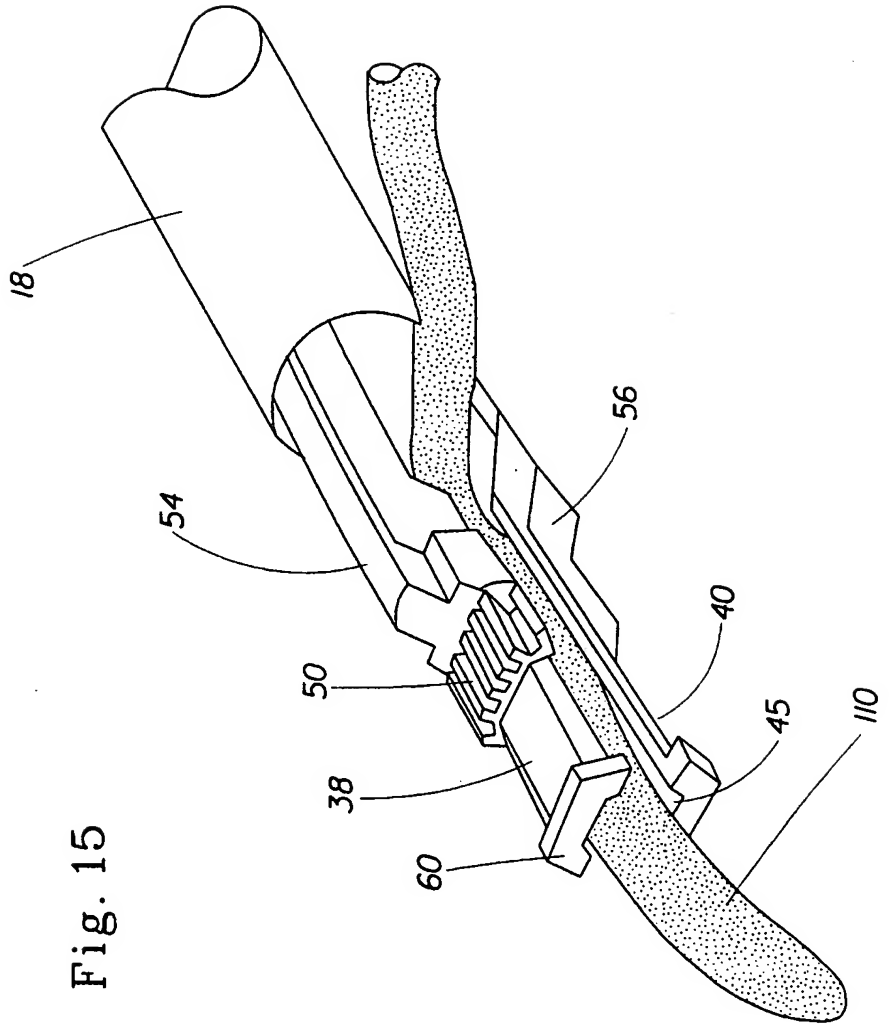

Fig. 15

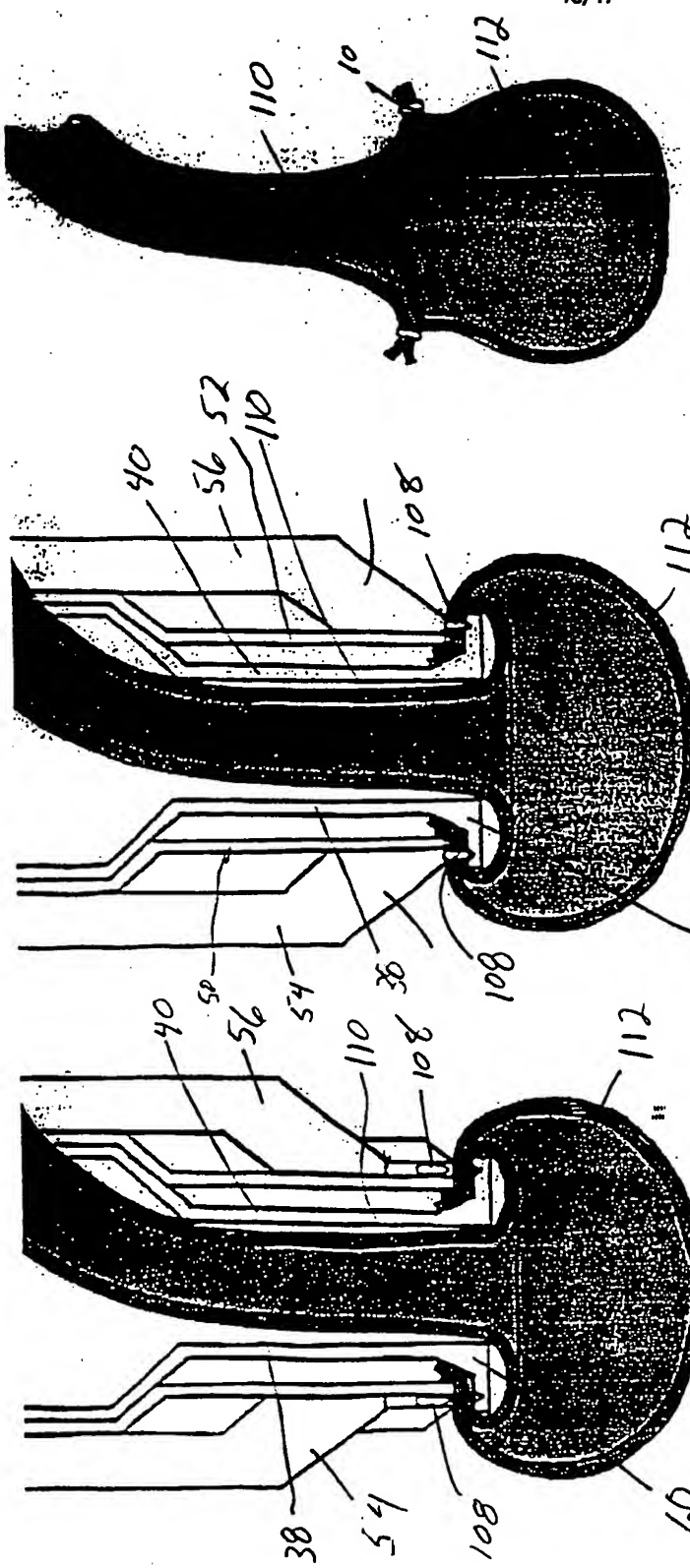

Fig. 20

Fig. 19

Fig. 18

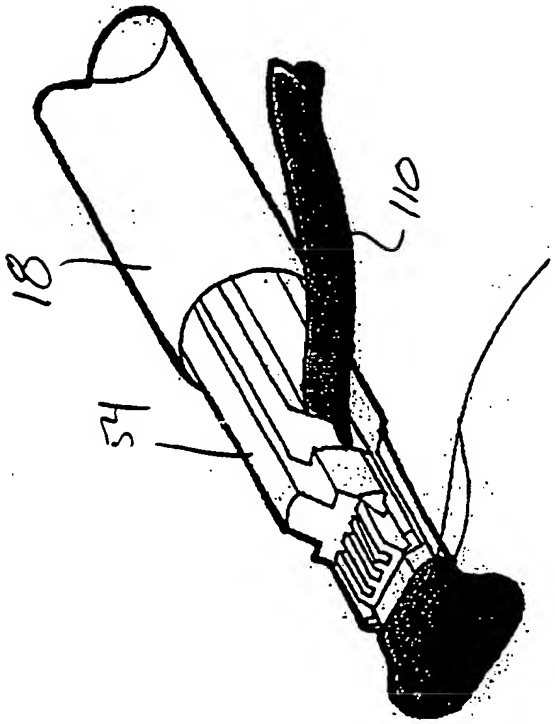

Fig 17

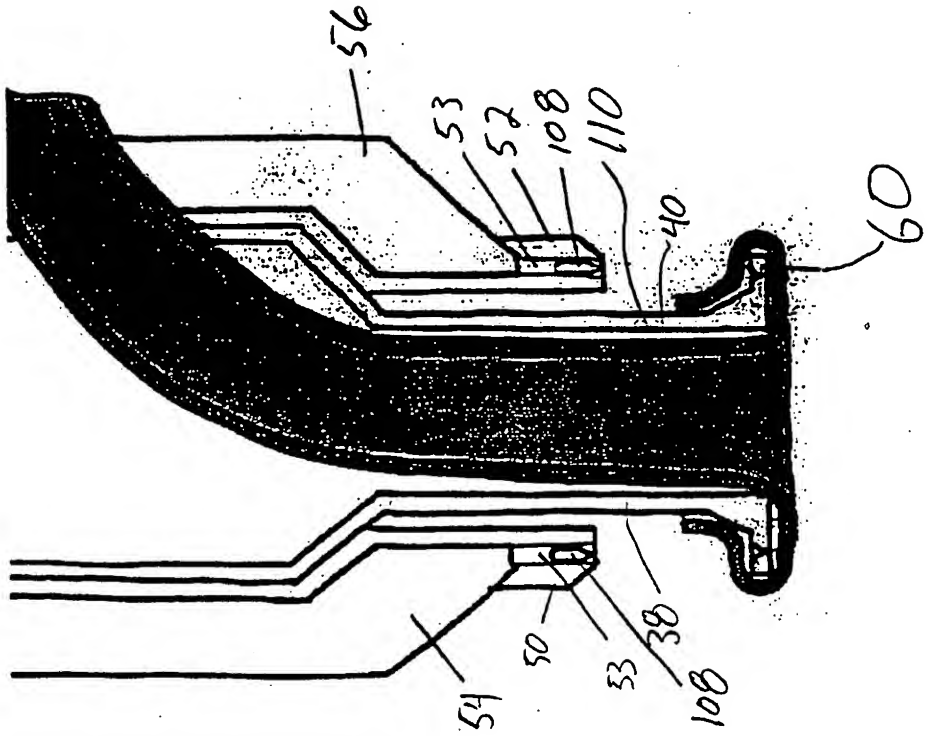

Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/18471

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/068
US CL :227/19, 176.1, 178.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 227/19, 175.1, 176.1, 178.1, 179.1, 180.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,484,451 A (AKOPOV et al.) 16 January 1996. See entire document.	1-15
A	US 5,551,622 A (YOON) 03 September 1996, See entire document.	1-15
A	US 5,669,918 A (BALAZS et al.) 23 September 1997, See entire document.	1-15
A	US 5,709,335 A (HECK) 20 January 1998, See entire document.	1-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 DECEMBER 1998

Date of mailing of the international search report

28 JAN 1999

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Form PCT/ISA/210 (second sheet)(July 1992)★